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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,895	03/20/2006	Yukiyo Sekimoto	2008_1706	1331

513 7590 02/19/2010  
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Washington, DC 20005-1503

EXAMINER
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MELLER, MICHAEL V

ART UNIT	PAPER NUMBER
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1655

NOTIFICATION DATE	DELIVERY MODE
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02/19/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ddalecki@wenderoth.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/572,895	<b>Applicant(s)</b> SEKIMOTO ET AL.	
	<b>Examiner</b> Michael V. Meller	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 8, 12, 13, 17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 12, 13, 17, 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/5/2009 and 11/30/2009</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election **without traverse** of Group I, claims 1-6, 12, 13 in the reply filed on 12/4/2007 is acknowledged.

Claims 7 and 8 remain withdrawn from further consideration as being drawn to non-elected inventions.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-5, 12, 13, 17, 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The claims are drawn to a soy isoflavone aglycone wherein the soy isoflavone aglycone is obtained from or in an extract from whole-grain soy; the genistein/daidzein weight ratio in the soy isoflavone aglycone is in the range of 1/1 to 1.5/1, and the proportion of the total weight of genistein and daidzein in the soy isoflavone aglycone is at least 90 %. Thus, the claims are drawn to a genus of compounds that is defined only by a nebulous percent and a nebulous ratio.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factors present in the claims are drawn to a soy isoflavone aglycone which is obtained from or in an extract from whole-grain soy; the genistein/daidzein weight ratio in the soy isoflavone aglycone is in the range of 1/1 to 1.5/1, and a soy isoflavone aglycone where the proportion of the total weight of genistein and daidzein in the soy isoflavone aglycone is at least 90 %. The specification gives no indication how such an amount of genistein and daidzein was obtained. In fact applicants have stated on the record that such an amount of genistein to daidzein does not naturally exist thus there is nothing on the record to show one of ordinary skill in the art that applicants had possession of the claimed invention at the time the invention was made since there is nothing to teach one of ordinary skill in the art in the specification

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how to identify such a compound. Without knowing what the compound's structure is, it is not in the possession of applicants. How can applicants be in possession of the claimed soy isoflavone aglycone "wherein the soy isoflavone aglycone is obtained from or in an extract from whole-grain soy" if applicants have stated on the record that the claimed compound is not always obtainable from soybeans as claimed ? Accordingly, in the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of inhibitors, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v.Revel, 25USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18USPQ2d 1016.

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One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, the claims do not meet the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Applicant alleges that the soy isoflavone aglycone has written description since how to make it is allegedly shown in JP 1987-126186 but such disclosure is not found in JP.

Next applicants argue that US 2001/0010930 (Obata) shows how the claimed aglycones can be made. It is stated at the top of page 6 of applicants specification that the claimed soy isoflavone aglycones can be obtained by, for example, extracting a glycoside from seeds (whole-grain soybeans) of *Glycine max* Merrill (Leguminosae 5 family) according to such a known method as disclosed in Japanese Unexamined Patent Publication No. 1987-126186, and subjecting the obtained glycoside to acid heating or beta-glucuronidase enzyme hydrolysis in a purification step. While this is noted, nowhere in Obata is it shown that the claimed soy isoflavone aglycones are obtained as describes above. In fact, no mention is made of an acid heating or beta-

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glucuronidase enzyme hydrolysis step. Even if it were, there is no disclosure in Obata that the soy isoflavones are 100 % aglycone. Applicants argue that the USDA reference does not represent only the amount of aglycone forms present in the soy flour but as evidenced in example 1-3 of Obata , it is stated that 90 % or more of the glycosides are converted to aglycone form but not all of the glycosides are converted to aglycone form.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 12, 13, 17, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lovett (US 6881419) in view of Obata et al. (US 2001/0010930).

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Lovett teaches that Vitamin D3, calcium and soy isoflavones (which inherently contain compounds such as genistein and daidzein) are in the same composition, see table 1. Note in the abstract that Lovett teaches that his supplement is used for osteoporosis as well as the prevention of it.

Note that about 27 % of calcium is used in the composition of Lovett,  $2.6 \times 10^{-4}$  % of Vitamin D<sup>3</sup> and about 2.4 % of soy isoflavones are used in the composition (when calculated with respect to the total composition).

Lovett does not teach the specifically claimed ratio of genistein/daidzein and the total weight of genistein and daidzein in the soy isoflavone aglycone is at least 90 %.

Applicant admits that Obata teaches the claimed amount of soy isoflavone aglycone. Further, Obata teaches that it was known at the time the invention was made that aglycones were known to be used for their antiosteoporosis activity.

Thus, it would have been obvious at the time the invention was made to use the soy isoflavone aglycones of Obata in the invention of Lovett since as applicant admits Obata teaches the claimed aglycones and at their claimed amounts. Lovett teaches use of his supplement for preventing osteoporosis and Obata teaches that aglycones were known for their antiosteoporosis activity thus it would have been obvious to use the composition of Lovett containing the aglycones of Obata in an effort to produce a composition which has improved activity against osteoporosis as taught by Obata.



3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael V. Meller/  
Primary Examiner, Art Unit 1655